UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION This document relates to: *County of Summit, Ohio, et al. v. Purdue Pharma L.P.,* Case No. 18-OP-45090 (N.D. Ohio); *County of Cuyahoga v. Purdue Pharma L.P.*, Case No. 17-OP-45004 (N.D. Ohio)	MDL No. 2804 Case No. 17-md-2804 Hon. Dan Aaron Polster

DEFENDANT NORMACO, INC.'S MEMORANDUM IN SUPPORT OF MOTION FOR JUDGMENT ON THE PLEADINGS OR, IN THE ALTERNATIVE, SUMMARY JUDGMENT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

RULES

STATUTES

OTHER AUTHORITIES

Defendant Noramco, Inc. ("Noramco") respectfully moves the Court to dismiss all claims against it in the Track One Complaints with prejudice, because Plaintiffs have not alleged facts—much less adduced evidence—that Noramco specifically engaged in any of the wrongful conduct alleged in the Track One Complaints. After numerous amendments, the combined 712 pages of operative Complaints make ***only one Noramco-specific allegation***: "Noramco is a Delaware company headquartered in Wilmington, Delaware, and was a wholly owned subsidiary of J&J and its manufacturer of active pharmaceutical ingredients until July 2016 when J&J sold its interests to SK Capital." Dkt. 1466 ¶ 74; Dkt. 1631 ¶ 67. The fact that Noramco is a former subsidiary of J&J, without more, is not sufficient, as a matter of law, to state a claim or for liability to attach.

Plaintiffs do not, and in fact, ***cannot*** allege that Noramco manufactured, sold, promoted, and marketed prescription opioids; nor do they (nor can they) allege that Noramco failed to maintain effective controls over the distribution of prescription opioids for this undisputed and incontrovertible fact: Noramco did not engage in any of the alleged illegal conduct at issue in this litigation. Unsubstantiated allegations, attorneys' arguments, and unfounded insinuations are ***not evidence***. In the over nine months this Court has permitted discovery to proceed in the Track One Cases, Plaintiffs have not requested that Noramco answer a single interrogatory, produce a single document, or produce a single witness for deposition testimony. Significantly, this Court acknowledged that "in order to hold a manageable trial, the number of claims and Defendants must be substantially reduced before the beginning of trial." Dkt. 1598 at 1-2. No discovery whatsoever has been taken of Noramco in this MDL, and no discovery of any Track One party, non-party, or expert has produced any evidence supporting Plaintiffs' claims against Noramco. Nonetheless, Plaintiffs have refused Noramco's request to be dismissed from these lawsuits—a request borne out of this Court's stated directive to the parties in its Civil Jury Trial Order.

It is black-letter law that the absence of evidence to support Plaintiffs' claims requires this Court to dismiss all Track One claims against Noramco. Justice, due process, fundamental fairness, and the applicable law all mandate Noramco's dismissal because Plaintiff's claims against Noramco fail as a matter of law. Whether based on the pleadings alone or the undisputed material facts outside the pleadings, the Court should dismiss the claims against Noramco with prejudice.

BACKGROUND AND INTRODUCTION

I. PLAINTIFFS' CLAIMS ARE LIMITED TO ALLEGED CONDUCT REGARDING MARKETING OR DISTRIBUTION OF PRESCRIPTION OPIOID DRUGS—PRODUCTS NORAMCO HAS NEVER MARKETED OR DISTRIBUTED

Plaintiffs acknowledge that their mammoth Track One Complaints assert claims against just two types of defendants: (1) "the pharmaceutical manufacturers of prescription opioid drugs" that engaged in an alleged "false marketing campaign" concerning "such drugs" (the "Marketing Defendants") and (2) "entities in the supply chain" for prescription opioid drugs that allegedly failed to monitor and restrict improper distribution of "those drugs" (the "Distributor Defendants"). Dkt. 1466 ¶ 1; Dkt. 1631 ¶ 1.

Plaintiffs assert two categories of claims against the Marketing Defendants. The thrust of the first category of claims (the "Marketing Claims") is that defendants engaged in improper promotion of prescription opioid drugs and that these promotional efforts contributed to the opioid crisis. Dkt. 1466 ¶¶ 2-3, 41; Dkt. 1631 ¶¶ 2-3, 36. Plaintiffs allege that defendants misrepresented the risks and benefits of prescription opioid drugs and nefariously used various marketing channels to promote and increase sales of such drugs. Dkt. 1466 ¶¶ 169-459; Dkt. 1631 ¶¶ 157-447. The focus of the second category of claims (the "Distribution Claims") is that defendants failed to adequately monitor distribution and prevent oversupply and diversion of prescription opioid drugs. Dkt. 1466 ¶ 493; Dkt. 1631 ¶ 480. For their injuries, Plaintiffs allege that defendants' alleged marketing and distribution conduct caused an array of generalized harm, including increased costs

associated with the opioid epidemic and decreases in available public funding. *See, e.g,* Dkt. 1466 ¶¶ 903, 949, 993, 1025-26, 1063-64; Dkt. 1631 ¶¶ 946, 991, 1035, 1067-68, 1106-07.

The "prescription opioid drugs," Dkt. 1466 ¶ 1; Dkt. 1631 ¶ 1, that are the sole subject of Plaintiffs' claims are, by definition, finished drug products in dosage forms intended to be used by patients, and lawfully available to patients only by prescription. *See, e.g.*, 21 U.S.C. § 353(b) (defining prescription drugs); 21 C.F.R. § 201.51 (addressing prescription drugs' "dosage forms" such as "tablet [or] capsule"); *id.* § 206.3 (defining "a finished dosage form, e.g., a tablet or capsule" as a "drug product"). Accordingly, this motion refers to the prescription opioids at issue as "finished drug products." Noramco does not manufacture or distribute (or market, promote, brand, or sell) any finished drug products. Declaration of William Grubb ("Grubb Decl.") ¶ 10 (attached hereto as Exhibit 1). Plaintiffs' pleadings contain no specific allegations otherwise, and Plaintiffs have not adduced any evidence suggesting otherwise through the discovery process.

II. NORAMCO'S ROLE AS A COMPONENT SUPPLIER IS SEPARATE, DISTINCT, AND DISTINGUISHABLE FROM THAT OF THE MARKETING AND DISTRIBUTOR DEFENDANTS

Noramco is in a different line of business than the defendants who marketed or distributed finished drug products. Noramco instead manufactures chemicals that are active pharmaceutical ingredients ("ingredients") used by other companies that manufacture and market finished drug products. *Id.* ¶ 4. Unlike the finished drug products addressed by Plaintiffs' claims, Noramco's ingredients cannot be sold lawfully for patient use, with or without a prescription. *See, e.g.*, 21 C.F.R. § 207.1 (explaining that an "active pharmaceutical ingredient" is an "unfinished drug"). The federal government tightly regulates Noramco's manufacture and sale of ingredients through the Drug Enforcement Administration ("DEA") and Food and Drug Administration ("FDA"). Grubb Decl. ¶ 5.

Noramco does not and cannot manufacture and sell more of its ingredients than DEA approves, and DEA also must approve Noramco's customers; DEA independently sets annual quotas that strictly limit the amount of ingredients Noramco can manufacture and sell and dictates precisely who can purchase them. *Id.* ¶ 7. Noramco's share of the market can change annually within the DEA-controlled market, but Noramco cannot expand the market for ingredients beyond the DEA's overall limits. *Id.* ¶ 9. In addition, Noramco manufactures ingredients in compliance with FDA regulations and according to finished drug product manufacturers' specifications. *Id.* ¶¶ 4, 6. Among other things, FDA carefully controls the amount of ingredients that Noramco's customers can include in their finished drug products. *See, e.g.*, 21 C.F.R. §§ 314.50(a)(1), (d)(1)(ii)(a) (FDA approval of finished drug product covers its "strength"); *id.* § 314.3 (defining "strength" according to the amount of active ingredient in a finished drug product).

After Noramco supplies ingredients to DEA-licensed finished drug product manufacturers, the finished drug product manufacturers are free to alter, process, or use those ingredients as necessary for the manufacture of their FDA-approved finished drug products. Grubb Decl. ¶ 9. Noramco has no involvement whatsoever in the manufacture, packaging, branding, marketing, promotion, distribution, or sale of any finished drug products. *Id.* ¶ 10. In addition, Noramco has no input into what medicines, formulations, or dosages FDA approves for patient use, nor does Noramco have any input regarding physicians' prescription of finished drug products for patient use or the sale and distribution of finished drug products to pharmacies. *Id.* ¶ 11.

Although Noramco was once a wholly-owned subsidiary of Johnson & Johnson ("J&J"), Noramco is and always has been an entirely independent entity from J&J and its other affiliated companies. *Id.* ¶ 12. Noramco has always had its own separate and independent company name and letterhead and has always owned its own operational and manufacturing facilities. *Id.* In

addition, Noramco has always operated as an autonomous entity, developed its own business plan, and set its own policies and objectives; even in its prior capacity as a J&J subsidiary, Noramco conducted its day-to-day operations with almost no input from J&J or its other affiliated companies. *Id.* ¶ 13. Noramco does not and never has participated in J&J's finished drug product business and thus has never had any role whatsoever in any decisions regarding what finished drug products to manufacture or sell and has never had any role in any marketing, advertising, or promotional decisions relating to finished drug products. *Id.* ¶ 14. Accordingly, there is no factual basis for lumping Noramco together with manufacturers of finished drug products, who allegedly promoted those finished drug products in a deceptive manner or failed to adequately monitor their sale and distribution after completion of the finished drug product manufacturing process.

III. THERE IS NO RECORD EVIDENCE SUPPORTING ANY OF PLAINTIFFS' CLAIMS AGAINST NORAMCO BECAUSE PLAINTIFFS FAILED TO DEVELOP ANY EVIDENCE THAT NORAMCO COMMITTED ANY ALLEGED WRONGDOING OR CAUSED PLAINTIFFS' ALLEGED DAMAGES

Throughout the lengthy and complex discovery process in this case, Plaintiffs failed to produce any competent evidence that Noramco committed any wrongdoing. Noramco received no requests from Plaintiffs for written discovery, documents, or depositions. Grubb Decl. ¶ 15. Other than to list Noramco as a defendant, Plaintiffs' experts' reports do not mention Noramco at all. *Id.* ¶ 16. To Noramco's knowledge, the only reference to Noramco in the voluminous record in this case appears in the deposition testimony of Plaintiffs' expert Dr. David Kessler, who mentioned in passing that he reviewed documents pertaining to Noramco in preparing his expert opinion, and asserted that these documents showed that J&J-affiliated companies participated in the development of ingredients used in the manufacture of finished drug products. Deposition of David A. Kessler, M.D. ("Kessler Depo.") at 100:12-24, 526:19-527:7, 724:13-15 (relevant excerpts attached hereto as Exhibit 2). The time for developing any further evidence regarding

Noramco's alleged role in the marketing or distribution conduct has run out. *See* Dkt. 232; Dkt. 876; Dkt. 1306.

ARGUMENT

I. NORAMCO IS ENTITLED TO JUDGMENT ON THE PLEADINGS

On consideration of a motion for judgment on the pleadings under Rule 12(c), the district court applies the same standard governing motions to dismiss under Rule 12(b)(6). *Hitchcock v. Cumberland Univ. 403(b) DC Plan*, 851 F.3d 552, 558 (6th Cir. 2017). Accordingly, the moving party is entitled to judgment on the pleadings if, taking as true the well-pleaded material allegations in the complaint, there is no material issue of fact and the moving party is entitled to judgment as a matter of law. *Coyer v. HSBC Mortg. Servs.*, 702 F.3d 1104, 1107-08 (6th Cir. 2012).

Under Rule 8, Plaintiffs must plead "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Plaintiffs' Complaints must contain "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 547 (2007). To avoid judgment on the pleadings, Plaintiffs must plead sufficient facts to support the "reasonable inference that the defendant is liable for the misconduct alleged." *HDC, LLC v. City of Ann Arbor*, 675 F.3d 608, 611 (6th Cir. 2012) (quoting *Albrecht v. Treon*, 617 F.3d 890, 893 (6th Cir. 2010); *see Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

Plaintiffs must do more than allege that all defendants collectively engaged in general misconduct; to state sufficient claims against Noramco, Plaintiffs must allege sufficient facts specific to Noramco, which give it "fair notice" of the factual grounds for Plaintiffs' claims. *See In re Darvocet, Darvon, and Propoxyphene Prod. Liab. Litig.*, 756 F.3d 917, 932 (6th Cir. 2014) (complaint did not give "fair notice" because it did not allege specific facts regarding any particular drug manufacturer's failure to implement appropriate warnings). In other words, "conclusory allegations of collective, unspecified, and undifferentiated wrongdoing [are] not sufficient:

'vaguely lump[ing] all defendants together without providing any factual allegations that specify separate acts' fails to satisfy the *Iqbal/Twombly* standard." *Kurek v. Ohio Dep't of Dev. Disabilities*, No. 3:16-cv-623, 2017 U.S. Dist. LEXIS 65473, at *15-16 (N.D. Ohio Jan. 20, 2017).[1]

Without reference to materials beyond the pleadings, the Court should dismiss Plaintiffs' claims against Noramco, because Plaintiffs pleaded insufficient factual information regarding Noramco to support a plausible claim for relief. Fed. R. Civ. P. 12(c). Plaintiffs allege no specific facts regarding Noramco's purported participation in the marketing and distribution conduct that forms the basis of their claims. *See generally* Dkt. 1466; Dkt. 1631. Nor do they allege any specific facts showing that Noramco conduct specifically caused the alleged injuries. *See id.* As to Noramco specifically, Plaintiffs merely allege that Noramco was a wholly-owned subsidiary of J&J and J&J's manufacturer of ingredients until July 2016. Dkt. 1466 ¶ 74; Dkt. 1631 ¶ 67. Indeed, in the body of each over 300-page Complaint, the word "Noramco" appears only three times. Dkt. 1466 ¶¶ 1, 74; Dkt. 1631 ¶¶ 1, 67.

The only other allegations that relate in any way to Noramco are general, unspecified allegations regarding undifferentiated wrongdoing of groups of defendants. Such collective allegations merely lump Noramco together with J&J and its other affiliated entities, all Marketing Defendants, or all defendants collectively.[2] But these "collective, unspecified, and undifferentiated" allegations of wrongdoing by broadly-defined groups of defendants are

[1] For their fraud-based claims, Plaintiffs "must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). Under the Rule 9 standard, Plaintiffs must allege "with specificity who has made the particular misrepresentations and when they were made" and cannot merely make "general averments of fraud attributed to 'the defendants.'" *Hoover v. Langston Equip. Assocs.*, 958 F.2d 742, 745 (6th Cir. 1992).

[2] *See, e.g.*, Dkt. 1466 ¶ 77 *et seq.* & Dkt. 1631 ¶ 70 *et seq.* (defining "Janssen" to include "J&J, Janssen Pharmaceuticals, OMP, and Janssen Pharmaceutica and their DEA registrant subsidiaries and affiliates" and using the term "Janssen" collectively throughout the complaint to refer to general, unspecified conduct); Dkt. 1466 ¶ 100 *et seq.* & Dkt. 1631 ¶ 94 *et seq.* (defining "Marketing Defendants" to include "Janssen" and using the term "Marketing Defendants" collectively throughout the complaint to refer to general, unspecified conduct).

insufficient to put Noramco on notice of the particular alleged misconduct that forms the basis of Plaintiffs' claims against it. *Kurek*, 2017 U.S. Dist. LEXIS 65473 at *15-16. Moreover, Plaintiffs' own allegations acknowledge that Noramco is an ingredient supplier and thus is not engaged in the same type of conduct—marketing and distribution of finished drug products—on which their collective allegations and broad claims are based. Dkt. 1466 ¶ 74 & Dkt. 1631 ¶ 67. Because Plaintiffs' collective allegations regarding defendant groups do not identify with sufficient particularity the Noramco-specific conduct that allegedly was wrongful or contributed to their purported injuries, these allegations cannot pass muster under the *Iqbal*/*Twombly* plausibility standard. *See, e.g., In re Darvocet*, 756 F.3d at 932. Accordingly, the Court should dismiss all claims against Noramco with prejudice, because Plaintiffs' allegations cannot support "the reasonable inference that [Noramco] is liable for the misconduct alleged." *HDC*, 675 F.3d at 611.

II. ALTERNATIVELY, NORAMCO IS ENTITLED TO SUMMARY JUDGMENT BECAUSE PLAINTIFFS CANNOT PRODUCE ADMISSIBLE EVIDENCE SUPPORTING ANY CLAIMS AGAINST NORAMCO

Under Rule 56, the moving party is entitled to summary judgment if it "shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). To show that there is no genuine dispute of material fact, the moving party can show "that an adverse party cannot produce admissible evidence to support the fact." Fed. R. Civ. P. 56(c)(1)(B). In other words, the moving party can show that it is entitled to summary judgment by "pointing out to the district court . . . that there is an absence of evidence to support the nonmoving party's case." *Max Arnold & Sons, LLC v. W.L. Hailey & Co.*, 452 F.3d 494, 499 (6th Cir. 2006) (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986)).

Once the moving party points to a lack of evidence supporting the claims against it, the nonmoving party must produce "more than a scintilla of evidence in support of its position . . . such that a jury could reasonably find for the plaintiff." *Michigan Protection & Advocacy Serv. v.*

Babin, 18 F.3d 337, 341 (6th Cir. 1994). Only facts "that might affect the outcome of the suit under governing law will properly preclude entry of summary judgment." *Sigley v. City of Parma Heights*, 437 F.3d 527, 533 (6th Cir. 2006). Plaintiffs cannot avoid summary judgment by creating a dispute about irrelevant facts or producing "grounds for speculation" about ancillary, non-dispositive factual issues. *See Chappell v. City of Cleveland*, 585 F.3d 901, 915-16 (6th Cir. 2009). To defeat summary judgment, Plaintiffs must produce evidence sufficient to support a jury finding in their favor on their claims against Noramco. *See Babin*, 18 F.3d at 341.

When a plaintiff undertakes no discovery, despite having ample time to do so, and cannot produce any evidence to counter the defendant's position, the defendant is entitled to summary judgment. *See Dowling v. Cleveland Clinic Found.*, 593 F.3d 472, 477-80 (6th Cir. 2010) (defendant entitled to summary judgment when plaintiff failed to propound discovery during extended discovery period and could not present evidence to defeat summary judgment); *accord Whitehead v. Bowen*, 301 F. App'x 484, 485, 489 (6th Cir. 2008); *Jones v. City of Akron*, No. 5:16-cv-2587, 2019 U.S. Dist. LEXIS 33940, at *21-26 (N.D. Ohio Mar. 4, 2019).

A. As a Mere Component Supplier, Noramco Did Not Engage in, and Cannot be Held Liable for, Manufacturers' and Distributors' Purportedly Wrongful Marketing and Distribution of Finished Drug Products

Noramco is separate, distinct, and distinguishable from the Marketing and Distributor Defendants in the Track One Complaints. Noramco, which merely provides ingredients to finished drug product manufacturers, is a component supplier whose conduct does not give rise to liability under any of the theories Plaintiffs advance here. Alleged conduct of Noramco's customers is not attributable to Noramco. *See Jacobs v. E.I. du Pont de Nemours & Co.*, 67 F.3d 1219, 1241 (6th Cir. 1995) (component part suppliers are not "guarantors of finished products over which they have little control" and it would be "contrary to public policy" to impose responsibility on them for a completed product); *Burrows v. Fastener Eng'rs*, 64 N.E.2d 838, 841 (Ohio Ct. App. 1992)

(a product supplier cannot be held liable for injuries caused by a consumer's conduct, over which the supplier had no control, and which rendered the product unsafe). Because Plaintiffs cannot produce admissible evidence showing that Noramco engaged in the allegedly wrongful marketing or distribution of finished drug products, Noramco is entitled to summary judgment on all claims.

Under the component supplier doctrine, the supplier of a component that is incorporated into a finished product ordinarily is not responsible for dangers posed by the finished product into which the component is incorporated. *See, e.g., Zager v. Johnson Controls, Inc.*, 18 N.E.3d 533, 540 (Ohio Ct. App. 2014). Although the component supplier doctrine applies in cases involving product defect and strict liability claims, the policy considerations underlying that doctrine are instructive here. Plaintiffs attempt to hold Noramco liable for conduct that occurred after integration of its component ingredients into the finished drug products, notwithstanding the (undisputed) fact that Noramco did not participate in such conduct.

It is unfair and unreasonably burdensome to charge component suppliers with the task of anticipating and preventing dangers posed by the conduct of finished product manufacturers and the final products they sell. *See, e.g., Childress v. Gresen Mfg. Co.*, 888 F.2d 45, 49 (6th Cir. 1989); *Temple v. Wean United, Inc.*, 364 N.E.2d 267, 272 (Ohio 1977). A component supplier like Noramco simply cannot control the decisions that finished drug product manufacturers and distributors make about marketing and distribution of finished drug products. *See* Restatement (Third) of Torts: Products Liability, § 5 cmt. a (1998) ("[I]t would be unjust and inefficient to impose liability [on the component seller] solely on the ground that the manufacturer of the integrated product utilizes the component in a manner that renders the integrated product defective. . . . This would require the component seller to . . . review the decisions of the business entity that is already charged with responsibility for the integrated product.").

Noramco's role in the production of opioids is fundamentally and decisively different from the role of finished drug product manufacturers and distributors. Noramco simply does not participate in any marketing or distribution of finished drug products—much less the allegedly wrongful marketing and distribution conduct on which Plaintiffs rely for their claims. Instead, Noramco merely supplies ingredients to finished drug product manufacturers in accordance with the manufacturers' specifications and as allowed by applicable law. Grubb Decl. ¶ 4. It is DEA, not Noramco, that dictates precisely which finished drug product manufacturers can receive Noramco ingredients, so Noramco is not even in full control of who receives its ingredients. *Id.* ¶ 7. Because of the regulatory safeguards under which Noramco operates its ingredient business, it cannot expand its sales of ingredients beyond the limits set by DEA quotas. *Id.* ¶ 8. As an ingredient manufacturer, Noramco has no involvement whatsoever in its customers' manufacture, packaging, branding, marketing, promotion, distribution, or sale of finished drug products. *Id.* ¶ 10. Noramco has no input regarding FDA approval of finished drug products for patient use, how physicians prescribe finished drug products for patient use, or the sale and distribution of finished drug products to pharmacies or other parties. *Id.* ¶ 11.

Plaintiffs have no admissible evidence to rebut these facts or to create a genuine dispute of material fact. Grubb Decl. ¶¶ 15-16. Because Plaintiffs failed to develop any such evidence through discovery, Noramco is entitled to summary judgment on all of Plaintiffs' claims, each of which is focused on conduct that allegedly occurred well after Noramco supplied other companies with ingredients for use in the manufacture of finished drug products. *See Dowling*, 593 F.3d at 477-80 (defendant entitled to summary judgment where plaintiff failed to adduce facts during discovery in support of claims); *accord Whitehead*, 301 F. App'x at 485, 489; *Jones*, 2019 U.S. Dist. LEXIS 33940 at *21-26. The conduct at issue in Plaintiffs' Complaints is separate and

distinct from Noramco's conduct and its limited role as a component supplier, and Plaintiffs' theories of liability simply do not apply to Noramco. *See Babin*, 18 F.3d at 341 (to defeat summary judgment, plaintiff must come forward with evidence sufficient to allow a jury to find in its favor).

B. Noramco's Discrete and Limited Conduct as a Component Supplier Is Not Causally Linked to Plaintiffs' Alleged Injuries, and the Absence of Proximate Cause Requires Judgment in Noramco's Favor

Noramco is also entitled to summary judgment because Plaintiffs cannot establish a causal link between Noramco's actual conduct and the injuries that Plaintiffs allege. For each of their substantive claims against Noramco, Plaintiffs are required to show that Noramco's conduct is the proximate cause of their alleged injuries. *See Hemi Group, LLC v. City of New York*, 559 U.S. 1, 9 (2010) (RICO); *Bradley v. Miller*, 96 F. Supp. 3d 753, 774 (S.D. Ohio 2015) (Ohio Corrupt Practices Act); *City of Cincinnati v. Deutsche Bank Nat'l Trust Co.*, 863 F.3d 474, 480 (6th Cir. 2017) (Public Nuisance); *Wallace v. Ohio*, 773 N.E.2d 1018, 1025-26 (Ohio 2002) (Negligence); *Jacobson v. Kaforey*, 75 N.E.3d 203, 207 (Ohio 2016) (Injury Through Criminal Acts).[3] Because Noramco played no role in the manufacture, marketing, or distribution of finished drug products, Plaintiffs cannot establish any causal link between their alleged injuries and Noramco's conduct.

Moreover, even if the conduct in which Noramco engaged—the mere supply of ingredients to finished drug product manufacturers—could somehow be linked to the scope of conduct that forms the basis of Plaintiffs' claims, those claims would still fail, because any connection between

---

[3] Plaintiffs' claim for unjust enrichment fails because it is derivative of the same conduct that forms the basis of Plaintiffs' other failed claims. *See McCarty v. Pedraza*, 17 N.E.3d 71, 80-81 (Ohio Ct. App. 2014); *Johnson v. Microsoft Corp.*, 834 N.E.2d 791, 799 (Ohio 2005). At any rate, Plaintiffs cannot produce any evidence showing that Plaintiffs conferred a benefit upon Noramco and, even if they could, it would not be wrongful for Noramco to retain such a benefit because Noramco did not engage in the allegedly wrongful marketing and distribution conduct relating solely to finished drug products. *See Hambleton v. R.G. Barry Corp.*, 645 N.E.2d 1298, 1302 (Ohio 1984).

As to Plaintiffs' derivative conspiracy claim, Noramco is entitled to summary judgment because Plaintiffs cannot establish any underlying tort and because Plaintiffs cannot produce any evidence showing that Noramco, which engaged in no conduct involving finished drug products, participated in any conduct that would constitute part of a concerted action to accomplish some unlawful purpose. *See Glassner v. R.J. Reynolds Tobacco Co.*, 223 F.3d 343, 354 (6th Cir. 2000); *Kerr v. Hurd*, 694 F. Supp. 2d 817, 832 (S.D. Ohio 2010).

Noramco's conduct and the injuries alleged would be too remote. To show that Noramco's conduct was the proximate cause of their injuries, Plaintiffs must demonstrate there is a "***direct relation*** between the injury asserted and the injurious conduct alleged." *City of Cleveland v. Ameriquest Mortg. Sec., Inc.*, 615 F.3d 946, 502 (6th Cir. 2010) (emphasis added) (quoting *Holmes v. Sec. InvestorProt. Corp.*, 503 U.S. 258, 268 (1992)).

It is well established that if multiple intervening factors disrupt the alleged connection between the defendant's conduct and the alleged injury, the injury is too remote, and the plaintiff's claim fails for lack of proximate causation. *See Ameriquest*, 615 F.3d at 504-05 (in an action brought by a city complaining that downstream financial entities harmed the city by participating in the market for mortgage-related investments, the city's injuries were too remote because the intervening actions of the originating lenders and sub-prime borrowers could have caused the injuries); *see also Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 457-58 (2006) (plaintiff could not satisfy the directness requirement where defendant's conduct in defrauding the state did not lead directly to the drop in the plaintiff's sales). If multiple additional contributing factors separate the defendant's conduct from the plaintiff's harm, "the remote connection between the alleged misconduct and the alleged injury makes it impossible 'to ascertain the amount of [] damages attributable to'" the defendant. *Ameriquest*, 615 F.3d at 505 (quoting *Holmes*, 503 U.S. at 269).

Here there are innumerable intervening factors that separate Noramco's actual conduct from the injuries that Plaintiffs allege. After Noramco supplies ingredients to the finished drug product manufacturers, a complex series of events must occur before Plaintiffs could suffer any of their alleged injuries. Multiple actors must intervene in multiple ways, including, just to name a few: (1) the finished drug product manufacturers must use the ingredients to formulate a finished drug product in a dosage form that could be made available lawfully to patients; (2) the finished

drug product manufacturers must promote their finished drug products to prescribers and patients; (3) the prescribing physicians must determine, and authorize, that individual patients should receive the finished drug products at certain dosages and for certain periods of time; (4) the pharmacies must dispense the finished drug products to patients in accordance with prescriptions; (5) the manufacturers and distributors of the finished drug products must monitor the sale and distribution of their products and make decisions about whether to report suspicious activity to DEA; (6) the manufacturers and distributors must continue to supply the market with the finished drug products despite allegedly suspicious increases in demand; and in at least some cases (7) bad actors must unlawfully divert the finished drug products to unauthorized users.

The list set forth above is not exhaustive, but it does illustrate that Noramco was simply unable to proximately cause Plaintiffs' injuries. The undisputed facts establish that Noramco did not, and could not, directly cause the opioid crisis and its attendant costs. The tenuous link between Noramco's supply of ingredients and Plaintiffs' alleged injuries is too remote. The complexity of the intervening causes renders Noramco's conduct so far removed from the claimed injuries that there cannot be a direct, actionable link between Noramco's supply of ingredients and those injuries. *See Ameriquest*, 615 F.3d at 503-05. Noramco thus is entitled to summary judgment on all claims. *See Babin*, 18 F.3d at 341.

C. Dr. Kessler's Testimony (and the Underlying Alleged Facts on Which He Relied) Do Not Establish a Material Factual Dispute and Therefore Cannot Preclude Summary Judgment in Noramco's Favor

To Noramco's knowledge, the only Track One discovery that even mentioned Noramco is a passing reference in the deposition testimony Plaintiffs' expert, Dr. David Kessler, who testified

in his deposition that he reviewed materials relating to Noramco.[4] Kessler Depo. at 100:12-101:24, 724:13-15. Dr. Kessler testified that he reviewed unspecified Noramco documents that demonstrated that Janssen and other affiliated entities allegedly participated in the development of a "super poppy," which allegedly "drove the increase in" oxycodone. *Id.* at 100:22-101:4, 526:19-527:7. Dr. Kessler conceded, however, that this contention was not part of his expert opinion; it was only factual information that he allegedly gleaned from unspecified materials that he reviewed. *Id.* at 526:22-23. Dr. Kessler acknowledged that he only intends to testify as an expert witness and will not testify as a fact witness. *Id.* at 530:13-16. Dr. Kessler further admitted that, other than to list it as a defendant, he did not mention Noramco once in his 315-page report and does not intend to offer any opinions regarding Noramco. *Id.* at 528:6-12, 528:15-22, 529:13-19, 529:24-530:1.

1. The Court Should Exclude Dr. Kessler's Specific Testimony About Noramco, Because He Has Admitted That it is Not Expert Testimony[5]

The Court also should exclude Dr. Kessler's specific testimony about Noramco. The testimony is plainly hearsay, because he does not purport to have any personal knowledge of the facts that he recited in his deposition. Under Fed. R. Evid. 703, inadmissible evidence such as hearsay may serve as a basis for an expert opinion and may even (under some limited circumstances) be disclosed to the jury if it supports an expert opinion. However, Dr. Kessler has admitted that he is not offering any expert testimony about Noramco. Kessler Depo. at 526:22-23, 528:6-12, 528:15-22, 529:13-19, 529:24-530:1.

[4] Noramco produced no documents during Track One discovery. Grubb Decl. ¶ 15. The authenticity of the documents on which Dr. Kessler relied thus is questionable. *See* Fed. R. Evid. 901. As explained below, the materials on which an expert relies cannot be offered for the truth of the matters asserted therein unless they are independently admissible.

[5] For the reasons set forth in the "Manufacturers' Motion to Exclude the Testimony of David A. Kessler, M.D. and Matthew Perri, III BS PHARM, Ph.D., RPh," ("Kessler Motion") the Court should exclude the testimony of Dr. Kessler altogether. Noramco incorporates those arguments as if set forth fully herein. If the Court grants the Kessler Motion, Plaintiffs then cannot rely on Dr. Kessler's testimony to defeat this motion.

The Federal Rules of Evidence preclude Dr. Kessler from simply parroting hearsay evidence when he bases no expert opinion on it, for that would simply be an impermissible end-run around the hearsay rule. Under those circumstances, "Rule 703 is simply inapplicable and the usual rules regulating the admissibility of evidence control." 29 Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 6273 at 312 & nn.22-23 (3d ed. 2008); *see United States v. Rios*, 830 F.3d 403, 418 (6th Cir. 2016) ("If an expert simply parrots another individual's out-of-court statement, rather than conveying an independent judgment . . . then the expert is, in effect, disclosing that out-of-court statement for its substantive truth.") (quoting *United States v. Pablo*, 696 F.3d 1280, 1288 (10th Cir. 2012)); *United States v. Mejia*, 545 F.3d 179, 198 (2d Cir. 2008) (expert precluded from simply transmitting hearsay to the jury without applying any expertise to it); *United States v. Smith*, 869 F.2d 348, 355 (7th Cir. 1989) (expert witness may not simply summarize out-of-court statements of others); *Ask Chems., LP v. Computer Packages, Inc.*, 593 F. App'x 506, 510-11 (6th Cir. 2014) (expert testimony excluded where the expert merely regurgitated information provided to him without independent analysis). Excluding Dr. Kessler's testimony would preclude any material factual dispute based on that testimony.[6]

2. Dr. Kessler's Testimony Would Not Create a Genuine Dispute of Material Fact Even if the Testimony Were Admitted

Furthermore, even assuming *arguendo* that Dr. Kessler's testimony about Noramco were admissible, it would not create a genuine dispute of material fact that would defeat summary judgment. Noramco's mere participation in the supply of ingredients is insufficient to support

[6] Dr. Kessler's hearsay likely would not be admissible even if he were offering an expert opinion in reliance upon it. Such materials could only be disclosed to the jury for the limited purpose of explaining the basis of the expert's opinion. *Engebretsen v. Fairchild Aircraft Corp.*, 21 F.3d 721, 729 (6th Cir. 1994). And the expert's inadmissible reliance materials can only be disclosed to the jury for that limited, non-substantive purpose "if their probative value in helping the jury evaluate the opinion substantially outweighs their prejudicial effect." Fed. R. Evid. 703; *Engebretsen*, 21 F.3d at 729. To defeat summary judgment, Plaintiffs would need to make that showing.

Plaintiffs' claims against Noramco, and therefore, cannot create a genuine dispute of material fact. *See Sigley*, 437 F.3d at 533 (only facts that "might affect the outcome of the suit" preclude summary judgment); *Chappell*, 585 F.3d at 915-16 (irrelevant facts about ancillary issues are immaterial). The "facts" that Dr. Kessler discussed in his deposition—that Janssen and other affiliated entities developed a "super poppy"—do not establish that Noramco engaged in the marketing or distribution of finished drug products or that Noramco's manufacture or supply of ingredients was the proximate cause of the Plaintiffs' alleged injuries. *See Sigley*, 437 F.3d at 533.

D. Noramco's Status as a Former Subsidiary of J&J Does Not Support Liability, and Therefore, Cannot Create a Genuine Dispute of Material Fact Sufficient to Defeat Noramco's Entitlement to Judgment as a Matter of Law

Finally, Noramco is not subject to "guilt by association." The Court should reject any argument that Plaintiff's claims against Noramco survive merely because the company previously was affiliated with entities such as J&J and Janssen (which did engage in the manufacture and marketing of finished drug products). Noramco always has been a separate entity from its former parent corporation J&J and other affiliated entities. Grubb Decl. ¶ 12. Throughout its existence, Noramco has operated as an autonomous business, created its own business plan, and set its own policies and objectives; even as a J&J subsidiary, Noramco conducted its operations independently from J&J and its other affiliated companies. *Id.* ¶ 13. Because it does not and never has participated in J&J's finished drug product business, Noramco does not and never has had any role in any decisions regarding which finished drug products J&J and its other affiliates manufactured or sold or in any marketing, advertising, or promotional decisions relating to finished drug products. *Id.* ¶ 14. Claims against Noramco's former affiliates cannot resurrect claims against Noramco itself. *See Bucyrus-Erie Co. v. General Products Corp.*, 643 F.2d 413, 418-19 (6th Cir. 1981) (discussing the extraordinary circumstances required to disregard corporate separateness and hold one entity responsible for actions of another). The Court should reject any attempt by

Plaintiffs to impute to Noramco the purportedly wrongful conduct of other entities involved in the actual manufacture, promotion, distribution, or monitoring of finished drug products.

CONCLUSION

In sum, Plaintiffs failed entirely to allege specific facts about Noramco's supposed role in the conduct at issue and adduced no evidence that Noramco committed any misconduct. Nor could they. As an ingredient supplier with no role in the manufacture, sale, promotion, or distribution of finished drug products, Noramco cannot be held liable for the alleged wrongful conduct that is the sole basis of Plaintiffs' claims. Allowing Plaintiffs to pursue their unsubstantiated claims against Noramco would violate basic principles of due process and fundamental fairness and would be inconsistent with the Court's directive in its Civil Jury Trial Order to narrow the parties and claims at issue in this exceedingly complex case. *See* Dkt. 1598 at 1-2. Accordingly, Noramco respectfully requests that the Court dismiss all claims against it with prejudice.

Dated: June 28, 2019

Respectfully submitted,

/s/ Daniel G. Jarcho
Daniel G. Jarcho
D.C. Bar No. 391837
ALSTON & BIRD LLP
950 F Street NW
Washington, DC 20004
Telephone: (202) 239-3254
Facsimile: (202) 239-333
E-mail: daniel.jarcho@alston.com

Cari K. Dawson
Georgia Bar No. 213490
Jenny A. Hergenrother
Georgia Bar No. 447183
ALSTON & BIRD LLP
1201 West Peachtree Street NW
Atlanta, GA 30309
Tel.: (404) 881-7000
Fax: (404) 881-7777
cari.dawson@alston.com
jenny.hergenrother@alston.com

LOCAL RULE 7.1(F) CERTIFICATION

I certify that these cases have been assigned to the Track One litigation track and that this Memorandum adheres to the page limitations set forth in the Amended Order Regarding Pretrial Motions for "Track One" Trial.

Dated: June 28, 2019

/s/ Daniel G. Jarcho
Daniel G. Jarcho
D.C. Bar No. 391837
ALSTON & BIRD LLP
950 F Street NW
Washington, DC 20004
Telephone: (202) 239-3254
Facsimile: (202) 239-333
E-mail: daniel.jarcho@alston.com

Cari K. Dawson
Georgia Bar No. 213490
Jenny A. Hergonrother
Georgia Bar No. 447183
ALSTON & BIRD LLP
1201 West Peachtree Street NW
Atlanta, GA 30309
Tel.: (404) 881-7000
Fax: (404) 881-7777
cari.dawson@alston.com
jenny.hergenrother@alston.com

CERTIFICATE OF SERVICE

I hereby certify that I served the foregoing on the Parties, the Court, and the Special Masters in accordance with the Court's directions in Dkt. 1719.

/s/ Daniel G. Jarcho
Daniel G. Jarcho